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5.0 510(k) Summary

SEP 1 2010

1. Sponsor

SpineFrontier, Inc.
500 Cummings Center
Suite 3500
Beverly, MA 01915

Primary Contact: John Sullivan
Telephone: 1- 978-232-3990

Date Prepared: December 7, 2009

2. Device Name and Classification:

Proprietary Names: ***Vega™ SPAN™* Spinous Process Plate System**

Common/Usual Name: Interlaminal Spinal Fixation Orthosis

Classification Name: Interlaminal Spinal Fixation Orthosis
(21 CFR 888.3050), Class II

Product Code: KWP

3. Predicate Devices

K073278 – Nuvasive Spinous Process Plate System
K071877 – Lanx Spinal Fixation System
K050675 – DePuy Expedium Spinous Process Plates

4. Device Description

The ***Vega™ SPAN™*** Spinous Process Plate System consists of plates of varying length and hub diameters, set screws, and instruments required for implantation. Spikes are present on the sides of the plate that interface with the spinous process to restrain the plate from rotating post-operatively. The device is offered with varying lengths and hub diameters to accommodate anatomical needs. Set screws are used to secure the two sides of the device into the final compressed and implanted construct.

System components are supplied non-sterile, are single use and are fabricated from titanium alloy (Ti-6Al-4V ELI) that conforms to ASTM F 136.

5. Intended Use

The ***Vega***™ ***SPAN***™ Spinous Process Plate System is a posterior non-pedicle supplemental fixation system intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion for the following indications: spondylolisthesis, trauma (fracture or dislocation), tumor, or degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies). The device is intended for use with bone graft material and is not intended for stand-alone use.

6. Technological Characteristics & Substantial Equivalence Determination

The SpineFrontier ***Vega***™ ***SPAN***™ Spinous Process Plate System was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles, and materials.

The ***Vega***™ ***SPAN***™ Spinous Process Plate System has been shown to be substantially equivalent to predicate devices in terms of performance (mechanical testing). Clinical data was not required for this device.

Mechanical testing included performance assessments of static and dynamic compression and torsion per methods described in ASTM F1717.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SpineFrontier, Inc.
% Mr. John Sullivan
Director of QA and Regulatory Compliance
500 Cummings Center, Suite 3500
Beverly, Masschusetts 01915

SEP 1 2010

Re: K102020
Trade Name: Vega™ SPAN™ Spinous Process Plate System
Regulation Number: 21 CFR 888.3050
Regulation Name: Spinal interlaminal fixation orthosis
Regulatory Class: Class II
Product Code: KWP
Dated: July 6, 2010
Received: July 19, 2010

Dear Mr. Sullivan,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K102020

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4.0 Indications for Use Statement

510(k) Number (if Known): K102020

Indications For Use:

The ***Vega™ SPAN™ Spinous Process Plate System*** is a posterior non-pedicle supplemental fixation system intended for use in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous process for the purpose of achieving supplemental fusion for the following indications: spondylolisthesis, trauma (fracture or dislocation), tumor, or degenerative disc disease (defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies). The device is intended for use with bone graft material and is not intended for stand-alone use.

Prescription Use: X **AND/OR** **Over-The-Counter Use:** _____
(Part 21 CFR 801 Subpart D) **(Part 21 CFR 807 Subpart C)**

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102020